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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/627,908

07/25/2003

Jiande Chen

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

10/31/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/627,908

Applicant(s)

CHEN, JIANDE

Examiner

Michael Kahelin

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 20-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>20070917; 20070924</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 20-26 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:
2. Inventions I (claims 1-19) and II (claims 20-26) are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require that the volume of the stomach be increased. The subcombination has separate utility such as use with a system that simply relaxes the stomach, but does not slow stomach emptying.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such

claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 20-26 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Arguments

3. Applicant's arguments filed 9/24/2007 have been fully considered but they are not persuasive. Applicant argued that the originally filed application contains support for the transitional phrase "consisting essentially of:" because the disclosure at page 9 that "[t]he present methods can also be used in combination with electrostimulation of other parts of the gastrointestinal tract" is in implicit disclosure that small intestine-alone stimulation is also an envisioned embodiment, and Examples 1 and 2 disclose positively recite only small intestine stimulation. In regards to Examples 1 and 2, the Examiner incorporates the response of the previous Office Action inasmuch as the lack of a positive recitation of other stimulation is not grounds for exclusion. In regards to the disclosure at page 9, Applicant arguments rely on the basis that "[t]he present methods" include stimulation of the small intestine alone. However, pages 7 and 8 list several disclosed methods where other areas are stimulated (e.g., antrum of the stomach, greater curvature of the stomach, etc.). Therefore, "[t]he present methods" of page 9

includes small intestine and stomach and "can also be used in combination with electrostimulation of other parts of the gastrointestinal tract".

4. Regardless of the support for "consisting essentially of:" under 35 USC 112(1), the transitional phrase is construed as "comprising" if there is "absent a clear indication in the specification or claims of what the basic and novel characteristics actually are".

The Examiner is of the position that Applicant's alleged implicit disclosure on page 9 can hardly be considered a "clear indication" that the "basic and novel characteristic" of the claimed invention is stimulation of the small intestine and the exclusion of stimulation of the stomach. The mere allegation that this is an implicit disclosure weighs against a determination this is a "clear indication".

5. In regards to the rejections under 35 USC 102(b), Applicant alleged that the previous Office Action relies on an incorrect inherency argument because slowing small intestine transit does not necessarily slow stomach emptying. The Examiner maintains the position presented in the previous Office Action that slowing small intestinal transit will inherently slow stomach emptying because the digestive tract is a closed system, and further directs Applicant to column 8, line 39 of Chen's disclosure: "it is desirable to slow down or attenuate gastric emptying".

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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7. Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation "consisting essentially of" is lacking support in the cited Examples 1 and 2. Although the examples do not positively recite stimulation of other organs, the examples also do not exclude stimulation of other organs.

8. Any negative limitation or exclusionary proviso must have basis in the original disclosure. The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement (See MPEP 2173.05(i)).

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-6 and 11-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. (5,690,691).

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11. In regards to claims 1 and 11, Chen et al. disclose multiple implantable devices comprising leads (70'-87') with connectors for attachment to a pulse generator (18, 20, and 22), wherein the leads are adjacent to the small intestine and provide electrical stimulation to slow stomach emptying (Fig. 5, elements 74-81).

12. In regards to claims 2, 12, and 13, electrical stimulation is provided to the duodenum (74) and the jejunum (77).

13. In regards to claims 3-6 and 14-17, the electrical stimulation provided is in the range of 2 to 15 pulses per minute (col. 9, line 29), about 0.1 to about 4 seconds (col. 9, line 36), and has a pause of 3-30 seconds between pulses (inherent of a frequency of 9-12.5 pulses per minute and duration of 0.1 sec.).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 7-10, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. in view of Mintchev et al. (6,449,511). Chen et al. disclose the essential features of the claimed invention except for pulses comprising micro-bursts within the frequency range of 5 to 100 Hz. Mintchev et al. teach of a gastrointestinal stimulator which applies electrical stimulation in bursts in the frequency range of 5-500 Hz (col. 19, line 15) to produce local circumferential contractions without

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causing any significant damage to the tissues (col. 19, line 51). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Chen et al.'s invention by providing stimulation in bursts of 5 to 100 Hz to produce local circumferential contractions without causing any significant damage to the tissues.

Conclusion

16. This is an RCE of applicant's earlier Application No. 10/627,908. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK

MWK
10/26/07

GEORGE R. EVANISKO
PRIMARY EXAMINER

10/26/07